IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8517

Bartle, C.J. August 19, 2010

Lawrence Bryson ("Mr. Bryson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Pamela Lawrence, Mr. Bryson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Edward M. Gilbert, M.D. Based on an echocardiogram dated September 18, 2002, Dr. Gilbert attested in Part II of Mr. Bryson's Green Form that claimant suffered from severe aortic regurgitation.[4] Based on such findings, claimant would be

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Gilbert also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

entitled to Matrix A-1, Level I benefits in the amount of $76,873.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Sherman G. Sorensen, M.D., stated that "[t]here is mild dilatation of the ascending aortic root." Dr. Gilbert, however, attested in claimant's Green Form that Mr. Bryson did not have aortic root dilatation greater than 5.0 cm. Under the Settlement Agreement, the presence of aortic root dilatation greater than 5.0 cm requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)d). As the Trust does not contest Mr. Bryson's entitlement to Level I benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In October, 2003, the Trust forwarded the claim for review by George A. Davis, M.D., one of its auditing cardiologists. In audit, Dr. Davis concluded that there was no reasonable medical basis for Dr. Gilbert's finding that claimant did not have aortic root dilatation greater than 5.0 cm. Dr. Davis measured claimant's aortic root at 5.5 cm and explained that claimant had a "[s]everely dilated aortic root and proximal aorta. The [aortic insufficiency] source is due to the malcoaptation of the central portion of the aortic leaflets due

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5. Under the Settlement Agreement, a claimant is entitled to Level I benefits for damage to the aortic valve if he or she is diagnosed with severe aortic regurgitation. See Settlement Agreement § IV.B.2.c.(1)(a).

to the dilatation of the aortic root, resulting in severe [aortic insufficiency]." Dr. Davis also stated that "there is [a] set of measurements in the record dated March 18, 1994, which indicates an aortic root diameter measurement of 5.12cm, indicating aortic root dilatation since that time."

Based on the auditing cardiologist's finding that claimant had aortic root dilatation greater than 5.0 cm, the Trust issued a post-audit determination that Mr. Bryson was entitled only to Matrix B-1, Level I benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a verified statement from Dr. Gilbert, wherein he observed:

> The auditor noted that the technician's report (made presumably during M-mode) from an echocardiogram [of] March 18, 1994, suggested aortic root and proximal aorta dilation. However the official interpretation by the Board Certified cardiologist, Robert E. Fowles, M.D., was that the great vessels were normal. Based on the official interpretation, it is more likely than not that the technician derived numbers which were erroneous. It would seem very unlikely that Dr. Fowles would not comment on such severe dilatation if it was indeed present.

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Bryson's claim.

(emphasis in original.)

The Trust then issued a final post-audit determination, again determining that Mr. Bryson was entitled only to Matrix B-1, Level I benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Bryson's claim should be paid. On September 20, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3958 (Sept. 20, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 28, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case, such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he did not have aortic root dilatation greater than 5.0 cm. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Bryson reasserts the arguments made in contest; namely, that the auditing cardiologist relied on the technician's report of claimant's March 18, 1994 echocardiogram rather than the "official interpretation" by the reviewing cardiologist. Mr. Bryson also asserts that his echocardiogram of attestation supports the conclusion that he did not have aortic root dilatation.

In response, the Trust contends that claimant's arguments mischaracterize the Trust's determination. According

to the Trust, the auditing cardiologist's finding with regard to claimant's aortic root dilatation was based on Mr. Bryson's September 18, 2002 echocardiogram and Dr. Davis referenced other medical records "merely as additional support for his finding." The Trust also argues that claimant did not refute the specific findings of the auditing cardiologist.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have aortic root dilatation greater than 5.0 cm. Specifically, Dr. Vigilante stated that "[t]he parasternal long axis view demonstrates severe dilation of the aortic root. The aortic root measured 5.9 cm in diameter."

In response to the Technical Advisor Report, claimant argues that it was incorrect for the Technical Advisor to base his findings on Mr. Bryson's September 18, 2002 echocardiogram. According to claimant, the issue is whether claimant had aortic root dilatation prior to the ingestion of Diet Drugs.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not contest the findings of the auditing cardiologist or the Technical Advisor that the echocardiogram of September 18, 2002, on which Mr. Bryson's Green Form is based, demonstrated aortic root dilatation greater than 5.0 cm. Specifically, Dr. Davis found that claimant's aortic root diameter was 5.5 cm. Dr. Vigilante concluded that

claimant's aortic root diameter was 5.9 cm. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits for an aortic valve claim if he or she has aortic root dilatation greater than 5.0 cm. See Settlement Agreement § IV.B.2.d.(2)(c)i)d). On this basis alone, claimant has failed to meet his burden in proving that there is a reasonable medical basis for his claim.

We also reject claimant's argument that the relevant inquiry is whether Mr. Bryson had aortic root dilatation greater than 5.0 cm prior to his ingestion of Diet Drugs. Unlike some of the other factors that reduce a claim to Matrix B-1, there is no temporal element associated with aortic root dilatation. Compare Settlement Agreement § IV.B.2.d.(2)(c)i)d) with Settlement Agreement § IV.B.2.d.(2)(c)iii)c) ("FDA Positive regurgitation (confirmed by Echocardiogram) prior to Pondimin® and/or Redux™ use for the valve that is the basis of the claim.").

Finally, to the extent claimant suggests that he is entitled to Matrix A-1 benefits because his aortic root dilatation did not cause his aortic regurgitation, such argument is misplaced. Causation is not at issue in resolving Mr. Bryson's claim for Matrix Benefits. Rather, claimant is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix

> Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if there is aortic root dilatation greater than 5.0 cm. We must apply the Settlement Agreement as written. Accordingly, claimant's argument that his March 18, 1994 echocardiogram demonstrates that he did not have aortic root dilatation greater than 5.0 cm prior to Diet Drug use, even if true, is irrelevant.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he did not have aortic root dilatation greater than 5.0 cm. Therefore, we will affirm the Trust's denial of Mr. Bryson's claim for Matrix A-1 benefits and the related derivative claim submitted by his spouse.